

Claims

- [c1] A medical device for injecting fluid into a tissue at a selected location in the tissue, comprising:
an infusion tube having distal and proximal ends and defining a lumen with an outlet proximate the distal end and through which fluid in the lumen can exit from the infusion tube;
a localizing wire fixedly mounted to the infusion tube and comprising an anchor; and
wherein the medical device is positioned to deliver fluid to the selected location within the tissue by inserting the distal end of the infusion tube into the tissue such that fluid released through the outlet will flow to the selected location and the anchor engages the tissue to fix the position of the infusion tube.
- [c2] The medical device of claim 1, and further comprising a retainer for fixedly coupling the localizing wire to the infusion tube.
- [c3] The medical device of claim 2, wherein the retainer comprises an adhesive bonding the localizing wire to the infusion tube.

- [c4] The medical device of claim 2, wherein the retainer comprises a bead encircling the localizing wire and received within the lumen.
- [c5] The medical device of claim 4, wherein the bead is imagable with at least one of the following imaging methods: MRI, X-ray, Ultrasound, and Mammography.
- [c6] The medical device of claim 2, wherein the retainer comprises the localizing wire being press-fit within the lumen.
- [c7] The medical device of claim 2, wherein at least a portion of the localizing wire is received within the lumen.
- [c8] The medical device of claim 7 wherein the outlet comprises at least one port extending from the lumen to the exterior of the infusion tube.
- [c9] The medical device of claim 8 and further comprising multiple ports radially spaced about the infusion tube.
- [c10] The medical device of claim 8 wherein the at least one port is formed by a generally circular opening formed in the infusion tube.
- [c11] The medical device of claim 10 wherein the at least one port is formed by a slit formed in the infusion tube.

- [c12] The medical device of claim 7 wherein the anchor is releasable to permit the repositioning of the infusion tube.
- [c13] The medical device of claim 12 wherein the anchor comprises a flexible hook.
- [c14] The medical device of claim 7 and further comprising at least one imaging marker provided on at least one of the infusion tube and anchor.
- [c15] The medical device of claim 14 wherein there are multiple imaging markers.
- [c16] The medical device of claim 15 wherein the imaging markers are spaced in a predetermined arrangement.
- [c17] The medical device of claim 6 wherein the infusion tube further comprises an inlet for introducing fluid into the lumen.
- [c18] The medical device of claim 17 and further comprising a syringe fluidly connected to the inlet to introduce fluid into the lumen from the syringe.
- [c19] The medical device of claim 18 wherein the syringe is removably coupled to the inlet.
- [c20] The medical device of claim 1 wherein the infusion tube comprises multiple, fluidly isolated lumens.

- [c21] The medical device of claim 20 wherein at least a portion of one of the lumens is filled with a fluid that functions as an imaging marker to aid in the imaging of the medical device.
- [c22] The medical device of claim 21 wherein the fluid is gadolinium.
- [c23] The medical device of claim 1 wherein the localizing wire is mounted to the infusion tube proximate the distal end.
- [c24] The medical device of claim 1 wherein the localizing wire extends through the lumen of the infusion tube.
- [c25] The medical device of claim 24 wherein the localizing wire extends coaxially through the lumen.
- [c26] The medical device of claim 24 wherein the infusion tube comprises multiple lumens and the wire extends through one of the multiple lumens.
- [c27] The medical device of claim 24 wherein the wire comprises a repositionable hook forming the anchor.
- [c28] The medical device of claim 1 wherein the localizing wire comprises a fiber optic thread.
- [c29] The medical device of claim 28 wherein the anchor com-

prises a hook mounted to the fiber optic thread.

- [c30] The medical device of claim 1 wherein the outlet comprises multiple ports extending through the infusion tube to establish fluid communication between the lumen and the exterior of the infusion tube.
- [c31] The medical device of claim 30 wherein the ports are spaced radially about the infusion tube.
- [c32] The medical device of claim 31 wherein the ports are arranged in at least one set, and the ports in the at least one set are at 90° relative to each other.
- [c33] The medical device of claim 30 wherein the ports comprise circular apertures.
- [c34] The medical device of claim 30 wherein the ports comprise slits.
- [c35] The medical device of claim 1 and further comprising imaging markers provided on at least one of the infusion tube and the localizing wire.
- [c36] The medical device of claim 35 wherein the imaging markers have at least one of the following characteristics: echogenic, radiopaque, magnetic resonance compatible.

- [c37] The medical device of claim 35, wherein the imaging markers are imageable using at least one of the following methods: MRI, X-ray, Ultrasound, and Mammography.
- [c38] The medical device of claim 35 wherein the imaging markers comprise helical coils.
- [c39] The medical device of claim 38 wherein the helical coils are located in the lumen.
- [c40] The medical device of claim 38 wherein the helical coils encircle the infusion tube.
- [c41] The medical device of claim 35 wherein the imaging markers comprise a label imprinted with ink.
- [c42] The medical device of claim 41 wherein the ink comprises tungsten.
- [c43] The medical device of claim 1 and further comprising a cannula for locating the infusion tube into the tissue, the cannula having a lumen sized to receive the infusion tube and localizing wire, wherein the infusion tube and localizing wire are received within the cannula lumen, the cannula is inserted into the tissue, and a portion of the infusion tube is exposed to the tissue from the cannula.

- [c44] The medical device of claim 43 and further comprising a syringe fluidly coupled to the infusion tube lumen for the delivery of the fluid to the infusion tube.
- [c45] The medical device of claim 44 and further comprising a releasable connector for releasably connecting the syringe to the infusion tube.
- [c46] The medical device of claim 45 wherein the releasable connector is a Luer-lock connector.
- [c47] The medical device of claim 46 wherein the releasable connector is connected to the infusion tube with a compression fitting.
- [c48] The medical device of claim 47 wherein the infusion is transparent or translucent to permit the exterior viewing of the fluid as it flows through the lumen.
- [c49] A method of injecting a fluid into a tissue mass using a localizing needle comprising an infusion tube defining a lumen, a localizing wire fixedly mounted to the infusion tube, and at least one imaging marker located on the infusion tube or localizing wire, comprising the steps of:
inserting the infusion tube and localizing wire into tissue mass;
locating the infusion tube at a predetermined location

within the tissue mass by imaging the imaging marker;
anchoring the localizing wire at the predetermined location to fix the position of the infusion tube within the tissue mass, and
delivering a fluid to the tissue mass through the lumen.

[c50] The method of claim 49 wherein the locating of the infusion tube comprises locating the infusion tube near a biopsy site in the tissue mass.

[c51] The method of claim 50 wherein the delivering of fluid comprises delivering fluid through at least one port in the infusion tube.

[c52] The method of claim 51 wherein the infusion tube is located near the biopsy site such that the fluid exiting the at least one port flows to the biopsy site.

[c53] The method of claim 52 and further comprising the step of detecting the movement of the fluid from the biopsy site to another location.

[c54] The method of claim 53 wherein the biopsy site is located within a human breast and the another location is a node of the human lymphatic system.

[c55] The method of claim 54 wherein the inserting step comprises inserting the infusion tube and localizing wire into

a cannula.

- [c56] The method of claim 55 wherein the cannula is inserted into the tissue prior to the insertion of the infusion tube and localizing wire into the cannula.
- [c57] The method of claim 56 wherein the cannula is withdrawn from the tissue mass after the locating of the infusion tube.
- [c58] The method of claim 49 and further comprising the step of detecting the movement of the fluid to a second tissue mass.
- [c59] The method of claim 58 wherein the tissue mass is a human breast and the second tissue mass is a node of the human lymphatic system.